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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/647,057

Applicant(s)

NAGARAJA ET AL.

Examiner

Padmavathi v. Baskar

Art Unit

1645

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-6 and 9-19 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,9-11,16,17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Amendment***

1. Applicant's amendment to first action on merits filed on 7/27/06 is acknowledged.

### **Election**

2. Applicant reiterates arguments drawn to examining 10 sequences and reiterates arguments that it is a normal Office practice to examiner 10 sequences and cites MPEP 803.04, 1192 O.G.68.

The argument has been considered but has not been found persuasive because The examiner followed the restriction practice MPEP 803.04 and accordingly properly set forth the restriction in the previous office action. Further, MP3P 803.04 does not state that 10 sequences must be searched but rather states that up to 10 sequences may be searched under certain circumstances as seen fit by the Director. However, given the size of sequence databases, the search of more than one sequence is an undue burden on the office. Thus for the reasons set forth previously and above, the restriction requirement is deemed to be proper and is therefore made FINAL.

It is noted for applicants convenience that after final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested (see § 1.181 AND 1.144).

### ***Status of claims***

3. Claims 1, 5, 6 and 16 have been amended.

New claims 18-19 have been added.

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Claims 2-3, 7-8 are canceled.

Claims 1, 4, 5, 6, 9-11, 17 and 18 are under examination with respect to SEQ.ID.NO:8.

Claims 12-15 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

***Claim Rejections - 35 USC § 112 first paragraph maintained***

4. The written description rejection of claims 1, 4, 5, 6, 9-11, 16, 17 and newly added claim 18 under 35 U.S.C. 112, first paragraph is maintained as set forth in the previous office action.

Applicant 7/27/06 states that people of ordinary skill in the art of manipulating nucleotide sequences as well as the proteins encoded by such nucleotide sequences have a good idea of the potential outcomes of a wide variety of manipulations of the nucleotide or protein sequence. Such knowledge permits them to make substitutions or variations which have very little or no effect on the function of the sequence. Thus, it is likely that sequences having at least 87% sequence homology with a specifically disclosed sequence in the present application would exhibit similar function with those sequences having a higher degree of sequence homology with the disclosed sequences and one of ordinary skill in the art would be able to easily construct sequences having 87% sequence homology with one of the disclosed sequences and retain the desired function of the sequence, without undue experimentation.

The arguments have been considered but have not been found persuasive because the Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other

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physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original). However, Applicant's specification does not disclose the structure and function of an isolated nucleotide sequence having a nucleotide sequence having at least about 87% sequence homology with a sequence that is a truncated form of SEQ ID No. 8, said truncated form having at least 1017 nucleotides, said sequence having at least about 87% sequence homology with a sequence selected from the group consisting of SEQ ID NO- 8-14, said sequence having at least about 95% sequence homology with a sequence selected from the group consisting of SEQ ID Nos. 8-14 and expression vector containing said nucleotide sequences. In the absence of a defined structure function relationship, neither the specification nor the claims as originally filed provide an adequate written description of the claimed invention.

5. The scope of enablement rejection for claims 1, 4, 5, 6, 9-11, 16, 17 and newly added claim 18 under 35 U.S.C. 112, first paragraph is maintained as set forth in the previous office action.

Applicant opines 7/27/06 that the skill in the art has greatly progressed since the cited references were published and therefore the scope of the claimed invention is enabled.

The argument has been considered but has not been found persuasive because Applicant's opinion, in the absence of objective evidence, especially given the lack of teaching drawn to structure function relationships in the specification as originally filed, is not persuasive.

***Claim Rejections - 35 USC 102 maintained***

6. The rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by Struck et al 1998 (U.S. Patent # 5,804,190) is maintained as set forth in the previous office action.

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Applicant states that the claims now require at least 87% homology over a 1017 nucleotide length portion of SEQ ID No. 8, therefore, Struck does not teach or suggest such a homologous region and therefore cannot be said to anticipate or even obviate the present claims.

The argument has been considered but has not been found persuasive because claim 11 does not require at least 87% homology over a 1017 nucleotide length portion of SEQ ID No. 8, but rather drawn to a n isolated nucleotide sequence which differs from that of claim 1 due to ---point mutations, deletions, insertions and rearrangements. The prior art reference meets the limitations of the claim for the reasons of record

***New rejections based on the amendment***

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1,6, 16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1,6, 16 and 18 recite "said truncated form having a length of at least 1017 nucleotides", "having a l length of at least 1017 nucleotides," and "said truncated form having therein at least 339 contiguous amino acid ". However, neither the specification nor the originally filed claims recite the specific lengths of truncated forms as presently claimed.

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**Conclusion**

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

10. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Albert Navarro can be reached on (571) 272-0861. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

  
Padma Baskar Ph.D.

SUSAN UNGAR, PH.D  
PRIMARY EXAMINER

